

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>42191</b>	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. <b>PCT/FI2005/050061</b>	International filing date (day/month/year) <b>03-03-2005</b>	Priority date (day/month/year) <b>05-03-2004</b>
International Patent Classification (IPC) or national classification and IPC <b>See Supplemental Box</b>		
Applicant <b>Biohit Oyj et al</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a.  (*sent to the applicant and to the International Bureau*) a total of 3 sheets, as follows:

sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b.  (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input checked="" type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand <b>27-12-2005</b>	Date of completion of this report <b>16-03-2006</b>
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer <b>Fernando Farieta/Els</b> Telephone No. +46 8 782 25 00

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Cover sheet**

**International patent classification (IPC)**

**G01N 33/74** (2006.01)

**G01N 33/573** (2006.01)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/FI2005/050061

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

the international application in the language in which it was filed  
 a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:  
 international search (Rules 12.3(a) and 23.1(b))  
 publication of the international application (Rule 12.4(a))  
 international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

pages 1 - 17 as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19

pages\* 18 - 20 received by this Authority on 27 - 12 - 2005

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

pages 1 - 4 as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_  
 the claims, Nos. 1 - 16 \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_  
 the claims, Nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.

PCT/FI2005/050061

**Box No. II Priority**

1.  This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
  - copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
  - translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2.  This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

The priority is considered valid.

**Box No. V** **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

Novelty (N)	Claims	<u>1-15</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	<u>1-15</u>	YES
	Claims	_____	NO
Industrial applicability (IA)	Claims	<u>1-15</u>	YES
	Claims	_____	NO

## 2. Citations and explanations (Rule 70.7)

Reference is made to the following document:

D1:WO 02/054084 A1

The document D1 is regarded as being the closest prior art to the subject-matter of amended claims 1-15, and shows methods for assessing the condition of the gastric mucosa, such as to diagnose gastric changes in the mucosa. D1 contemplates determining the same markers, namely PGI, gastrin and a H. pylori marker.

However, D1 compares the measured marker concentrations with a predetermined cut-off value for the said marker, then forms a specific combination of such obtained comparison results and, based on this combination, it makes a diagnosis.

The subject-matter of amended claims 1-15 in the present application concerns a method based on quantification of a prediction. Therefore differs from this known method in D1 in that the probability is analyse for defined gastric mucosa classes in order to make a diagnosis. The subject-matter of claims 1-15 is therefore novel (Article 33(2) PCT).

-The problem to be solved by the present invention may therefore be regarded as improved methods for detecting gastric mucosa diseases.

-The solution to this problem proposed in amended claims 1-15 of the present application is considered as involving an inventive step (Article 33(3) PCT).

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/FI2005/050061
--

## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 70.10)

	Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
P, A	US6696262B2	24.02.04	14.03.01	15.11.95
P, X	WO2004/023148	18.03.04	05.09.03	06.09.02

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)